UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARTHA AND PETER PALUMBO, and JAYNE EHRLICH AND ANNA MURRET, Individually, and on Behalf of all Other Persons and Entities Similarly Situated,	09cv 6136 (DAB)
PLAINTIFFS,	SUIT NO:_____
vs.	
FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC.,	DIVISION:_____
	JURY TRIAL DEMANDED
DEFENDANTS.	

CLASS ACTION COMPLAINT

I. INTRODUCTION

1. Plaintiffs, Martha and Peter Palumbo, Jayne Ehrlich and Anna Murret, individually and as representatives of all persons and entities similarly situated, by their Attorneys Pogust, Braslow & Millrood, LLC, and Pendley, Baudin & Coffin, L.L.P., allege as follows:

2. This is a class action suit brought pursuant to the provisions of the Rule 23 of the Federal Rules of Civil Procedure, by Plaintiffs Martha and Peter Palumbo, Jayne Ehrlich and Anna Murret, individually, and on behalf of all other persons and entities similarly situated (hereinafter referred to as "Plaintiffs" or "Representative Plaintiffs") who are residents of the United States, to obtain relief from Defendants, Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc., (collectively referred to as "Defendants"), based on the causes of action stated below.

II. THE PARTIES

3. Plaintiffs, Martha and Peter Palumbo, are a citizens of the Commonwealth of Pennsylvania, domiciled in the city of Bradford located in McKean County. Plaintiffs Martha and Peter Palumbo paid, in whole or in part, for Lexapro and Celexa for use by her minor child. Plaintiff, Jayne Ehrlich, is a citizen of the State of Connecticut, domiciled in the city of Redding, located in Fairfield County. Plaintiff, Jayne Ehrlich, paid in whole or in part for Lexapro and Celexa used by her minor child. Plaintiff, Anna Murret, is a citizen of the State of Texas, domiciled in the city of Allen, located in Collin County. Plaintiff, Anna Murret, paid in whole or in part for Lexapro and Celexa for use by her minor child. Plaintiffs are members of the Plaintiff Class defined herein, and Plaintiffs will adequately represent the interests of the Plaintiff Class as the class representatives in this case.

4. Defendant Forest Laboratories, Inc., is a pharmaceutical company organized under the laws of Delaware with its principal place of business in New York, New York, and regularly conducts business within all states in the United States, and derives substantial revenues from goods consumed in the United States. Forest Laboratories has a license from H. Lundbeck A/S ("Lundbeck"), a Danish company, to promote and sell Celexa and Lexapro in the United States.

5. Defendant Forest Pharmaceuticals is a wholly owned subsidiary of Forest Laboratories with its principal place of business in St. Louis, Missouri. Forest Pharmaceuticals manufacturers, distributes, and sells Forest prescription products in the United States.

III. JURISDICTION AND VENUE

6. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d), because there are 100 or more class members and the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and cost, and at least one member of the class is a citizen of a different State than the Defendants.

7. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a). At all relevant times herein, Defendants, Forest Laboratories, Inc. ("Forest Labs"), and Forest Pharmaceuticals, Inc.

("Forest Pharmaceuticals") (collectively referred to hereinafter as "Forest"), transacted business within this District, and Defendants marketed and made material omissions and misrepresentations in this District. Additionally, Defendant Forest Labs resides in this District.

8. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because (1) a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this district and (2) the defendants are subject to personal jurisdiction in this district.

IV. NATURE OF THE CASE

9. Forest engaged in a fraudulent scheme to market and promote Celexa (citalopram) and Lexapro (escitalopram) off-label to treat depression and other psychiatric conditions in pediatric patients. Forest did so even though the Food and Drug Administration ("FDA") had not approved the drugs as safe and effective for any use in the pediatric population. In the case of Celexa, the FDA had specifically denied approval for any pediatric use.

10. Forest disseminated and caused others to disseminate false and misleading information to doctors and the public about the safety and efficacy of Celexa and Lexapro in treating pediatric patients. The company failed to disclose the negative results of a large, placebo-controlled study that found Celexa no more effective than placebo for pediatric use and in which more patients taking Celexa attempted suicide or reported suicidal ideation than those taking only placebo.

11. Forest sought to induce physicians and others to prescribe Celexa and Lexapro by providing them with various forms of illegal remuneration, including cash payments disguised as grants or consulting fees, expensive meals and lavish entertainment, and other valuable goods and services.

12. As a result, Plaintiffs and the putative class members have suffered damage, and Forest has been unjustly enriched. Forest sells citalopram and escitalopram in the United States under the trade names Celexa and Lexapro, respectively. Large numbers of medical providers, their minor patients, and their minor patients' guardians in these states, including the Plaintiffs herein, have been being misled about the drug's true efficacy and risks.

13. Plaintiffs thus respectfully ask the Court to: (a) award restitution and/or damages in the amount that was paid for the minors' Celexa and Lexapro prescriptions, plus interest; and (b) award all other costs, including attorneys' fees, available under the law.

V. CLASS ALLEGATIONS

14. Under Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs bring this action on behalf of themselves and all others similarly situated and on behalf of the general public as a putative class, defined as follows:

> "All persons and entities in the United States and its territories (other than state governmental entities) who purchased and/or paid, in whole or in part, for Celexa or Lexapro under the trade names of Citalopram or Escitalopram, during the period from 1998 through the present (the "Class Period") for consumption by a minor.

15. This action has been brought and may properly be maintained as a class action satisfying the numerosity, commonality, typicality, adequacy, and superiority requirements, because:

a. Individual joinder of Class Members would be impracticable. Plaintiffs, upon information and belief, allege that the class consists of tens of thousands of persons and entities.

b. Common questions of law and fact exist as to all members of the Class that predominate over any question that affects only individual Class Members. These common questions of law and fact include, without limitation, whether:

1) Forest has deceived and continues to deceive the medical community, including those providers who prescribed Celexa and Lexapro to minors, into believing Celexa and Lexapro does not have the harmful properties and the risks which Forest knows it in fact does;

2) Forest has deprived and continues to deprive medical providers the ability to perform the benefit/risk assessment necessary to determine if the use of Celexa and Lexapro for their child and adolescent patients is appropriate;

3) By Forest's concealment or provision of inaccurate or biased information that is material to a prescribing decision, it has misled and continues to mislead health care providers and patients who rely on their health care providers' professional judgment;

4) Forest has improperly sought to promote and continues to promote its drug Celexa and Lexapro at the expense of the health and welfare of those children and adolescents who have been prescribed the drug;

5) Forest has prevented and continues to prevent physicians from properly and independently exercising their professional judgment on behalf of their child and adolescent patients;

6) Forest has promoted directly or indirectly that Celexa and/or Lexapro is either safe or efficacious for treating depression in children and/or adolescents;

7) Forest has participated in "Ghostwriting" letters and articles for the signature of "opinion leaders" to be placed in respected medical journals, which downplay Celexa and Lexapro's adverse effects, promoting positive study outcomes and avoiding negative ones;

8) Forest has illegally paid kickbacks to physicians to induce them to prescribe the drugs;

9) Forest has disseminated and caused others to disseminate false and misleading information to doctors and the public about the safety and efficacy of Celexa and Lexapro in treating pediatric patients;

10) Forest has actively touted pediatric use of the drugs, while failing to disclose the negative results of a large, placebo-controlled study that found Celexa no more effective than placebo for pediatric use and in which more patients taking Celexa attempted suicide or reported suicidal ideation that those taking only placebo;

11) Forest has induced physicians and others to prescribe Celexa and Lexapro by providing them with various forms of illegal remuneration, including cash payments disguised as grants or consulting fees, expensive meals and lavish entertainment, and other valuable

goods and services, all in violation of the federal anti-kickback statute, 42 U.S.C. 3120a-7b(b) ("AKS").

12) Forest has intentionally or negligently miscoded adverse events;

13) Forest has intentionally failed to accurately and/or fully report known adverse effects of Celexa and Lexapro;

14) Forest has used "statistical sophistication" to manage unfavorable data from clinical studies;

15) Forest has been unjustly enriched.

c. The representative plaintiffs' claims are typical of those of the Class because they are residents of the United States who purchased and/or paid, in whole or in part, for Celexa and Lexapro for consumption by a minor.

d. The Representative Plaintiffs are adequate representatives of the Class because they share the same interest as all Class Members and because their claims and losses are typical of those of the Class Members. The Representative Plaintiffs have retained competent counsel who are experienced in class action litigation and who will fairly and adequately protect the interests of the Class Members.

e. A class action is superior to other available methods for the fair and efficient adjudication of this litigation, since individual joinder of all persons and entities who purchased and/or paid for Celexa and Lexapro in the United States for consumption by a minor is impracticable. Such losses are modest in relation to the expense and burden of individual prosecution of the litigation necessitated by the Defendants' wrongful conduct. It would be virtually impossible for the Class Members to efficiently redress their wrongs individually. Even if all Class Members themselves could afford such individual litigation, the Court system would benefit from a class action. Individualized litigation would present the potential for inconsistent or contradictory judgments. Individualized litigation would also magnify the delay and expense to all parties and to the Court system presented by the issues of the case. By contrast, the class action device presents far

fewer management difficulties and provides the benefit of comprehensive supervision by a single Court, as well as economy of scale and expense.

VI. FACTUAL ALLEGATIONS

16. Forest is a pharmaceutical manufacturer who has engaged in repeated and persistent fraud by misrepresenting, concealing and otherwise failing to disclose to physicians and other prescribing providers information in its control concerning the safety and effectiveness of Celexa and Lexapro as it relates to minors.

17. Celexa and Lexapro are closely-related selective serotonin reuptake inhibitor ("SSRIs") drugs. Lundbeck developed both Celexa and Lexapro, which contains the active agent in Celexa, and subsequently licensed both drugs to Forest for marketing in the United States. Forest began selling Celexa in 1998. In 2002, with Celexa soon due to face generic competition, Forest began selling Lexapro.

18. In 1998, Celexa was approved by the United States Food and Drug Administration ("FDA") as safe and effective for treating various indications in adults. The FDA has never approved Celexa for treatment of any conditions other than adult depression, or for any pediatric use.

19. In 2002, the FDA approved Lexapro for the treatment of adult depression. In 2003, Lexapro received approval for treatment of Generalized Anxiety Disorder ("GAD") in adults. Lexapro has not been approved for any other conditions and was not approved for pediatric use at the time Plaintiffs and the putative class members purchased the drug.

20. When Plaintiffs and the putitive class members purchased Celexa and/or Lexapro, neither drug carried "medically accepted" indication for use in the pediatric population. Celexa has never obtained an indication for use in the pediatric population.

21. Nevertheless, physicians are permitted to prescribe FDA-approved drugs for conditions or diseases for which FDA approval has not been obtained when, through the exercise of independent professional judgment, the physician determines the drug in question is an appropriate

treatment for an individual patient. This practice is referred to as "off-label" use, and prescribing Celexa and Lexapro for unapproved uses or for minors is off-label use.

22. Forest has misrepresented information concerning the safety and efficacy of Celexa and Lexapro for treating children and adolescents. For instance, Forest has allowed positive information about pediatric use of Celexa and Lexapro to be disclosed publicly, but has withheld and concealed negative information concerning the safety and effectiveness of the drug as a treatment for pediatric patients. Thus, Forest has prevented physicians from properly and independently exercising their professional judgment on behalf of their child and adolescent patients. Accordingly, Forest's acts have deprived these youngsters of the benefit of their physicians' independent professional judgment.

23. The FDA does not regulate the practice of medicine. The regulation of the practice of medicine is solely the responsibility of the individual states.

24. Physicians owe their patients fiduciary and professional obligations to exercise their independent professional judgment in making treatment recommendations and to recommend only those treatments that are appropriate for the individual patient. Conversely, patients (and, in the case of children and adolescents, their parents and guardians) rely on the professional judgment of their physicians in deciding whether to consent to and purchase a treatment.

25. Licensed physicians are permitted to prescribe a drug for conditions or diseases for which FDA approval has not been obtained when, in the physician's professional judgment, it is an appropriate treatment for the individual patient, provided the drug has already been approved by the FDA for some other use. This judgment is based on the balance between (a) the benefit the patient is likely to derive from the treatment, including the harm or benefit, if any, of providing no treatment or an alternative treatment, and (b) the risk that the proposed treatment will cause the patient harm and the nature and severity of that harm.

26. In deciding whether to prescribe a drug for an off-label use, physicians typically rely on their assessment of information received about the drug. Such information must be accurate and

provide an unbiased picture of a drug's safety and efficacy in treating a condition. If the information is false or misleading, the physician cannot accurately assess the crucial risk/benefit balance for the patient or exercise professional judgment that is independent. Consequently, the physician cannot act in accordance with the professional and fiduciary obligations owed to the patient.

27. Concealing or providing inaccurate or biased information that is material to a prescribing decision misleads the physician and the patient who relies on that physician's professional judgment.

Forest's Studies Concerning the Safety and Efficacy of Celexa and Lexapro in Treating Children and Adolescents

28. In August 1998, Forest submitted a "Proposed Pediatric Study Request for Celexa." On April 28, 1999, the FDA issued a Written Request to Forest to conduct "two independent, adequate and well-controlled clinical trials in pediatric depression" for Celexa.

29. On September 24, 1999, Forest submitted to the FDA protocols for two pediatric studies: 1) a double-blind, placebo-controlled pediatric study being conducted in Europe by Lundbeck (the "Lundbeck study"); and 2) a double-blind, placebo-controlled pediatric study to be conducted in the United States by Forest through University of Texas child psychiatrist Karen Wagner (the "Wagner study").

Efficacy

30. In mid-2001, the Wagner and Lundbeck studies were unblinded and their results were disseminated to senior Forest executives. The Wagner study was positive, i.e., it indicated that Celexa was more effective than placebo in treating pediatric patients suffering from depression, but the Lundbeck study was negative, *i.e.*, it did not show Celexa to be any more effective than placebo in treating pediatric depression. Furthermore, in the Lundbeck study, 14 of the patients taking Celexa attempted suicide or reported suicidal ideation (*i.e.*, contemplation of suicide) compared to only 5 patients taking placebo. Under one statistical test, this result was "significant" and, under another statistical test, it was "borderline significant."

31. On April 18, 2002, Forest submitted the results of both the Lundbeck and Wagner studies to the FDA in support of requests for both a six-month extension of patent exclusivity and a pediatric indication for Celexa. Forest's submission to the FDA was not public.

32. On July 15, 2002, the FDA granted Celexa six additional months of patent exclusivity for the on-label use of treating depression in adults.

33. On September 23, 2002, the FDA denied Forest's request for a pediatric indication for Celexa. The FDA concluded that the Lundbeck study "is a clearly negative study that provides no support for the efficacy of citalopram in pediatric patients with [major depressive disorder]."

Safety

34. On March 22, 2004, the FDA issued a public health advisory requesting that certain SSRI manufacturers, including Forest, change the labels on their SSRI drugs to include "a warning statement that recommends close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality."

35. Later that year, the FDA directed the SSRI manufacturers, including Forest, to include on their labels a black box warning and expanded statements to alert physicians about the potential for increased risk of suicidality in children and adolescents taking SSRIs. The black box warning specifically stated that "antidepressants *increased the risk* of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders." (Emphasis added). In addition, the FDA required SSRI manufacturers to state, in relevant part, that:

> The risk of suicidality for these drugs was identified in a combined analysis of short-term (up to 4 months) placebo-controlled trials of nine antidepressant drugs, including the selective serotonin reuptake inhibitors (SSRIs) and others, in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders. A total of 24 trials involving over 4400 patients were included. The analysis showed a greater risk of suicidality during the first few months of treatment in those receiving antidepressants.

36. The Lundbeck study on pediatric use of Celexa was one of the 24 trials considered by the FDA in mandating this warning.

37. The Celexa and Lexapro labels were revised by Forest in early 2005 to include the required black box warning and to state under each label's "Pediatric Use" subheading that "safety and effectiveness in the pediatric population have not been established (see BOX WARNING and WARNINGS-Clinical Worsening and Suicide Risk)." Further, the Celexa label stated that "two placebo-controlled trials in 407 pediatric patients with MDD have been conducted with Celexa, and the data were not sufficient to support a claim for use in pediatric patients," while the Lexapro label stated that "one placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients."

38. In 2007, the Celexa and Lexapro labels were again modified to state that, after evaluating the pooled analyses of placebo-controlled SSRI trials in children and adolescents and of trials in adults, "there was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied."

39. To date, Forest has not obtained FDA approval for a pediatric indication for Celexa. Both the Celexa and Lexapro labels currently include black box warnings explicitly indicating that the safety and efficacy of the drugs in the pediatric population have not been established.

Forest's Presentation of Positive Information and Misrepresentation and Suppression of Negative Information Regarding Celexa Usage for Minors

40. Although Forest submitted the Lundbeck study to the FDA in 2002 in order to seek a six-month extension of patent exclusivity for Celexa, Forest failed otherwise to disclose the negative study beyond a small group of its senior executives. At the same time, Forest aggressively promoted the Wagner study, thereby relaying the false impression that the only available pediatric data on Celexa was positive.

41. Although the Forest senior executives learned about the negative Lundbeck results in mid-2001, Forest failed for the next three years to disclose that negative data to, among others: its thousands of sales representatives who were detailing pediatric specialists; pediatric specialists whom it hired to give promotional speeches on Celexa and Lexapro; the members of its Executive Advisory Board of leading psychiatrists upon whom it ostensibly relied for advice concerning new data and upon whom it also relied to convey information to others; its own Professional Affairs Department, which it charged with disseminating "balanced" information in response to physician requests for available data on Forest drugs; or even its own pediatric researchers such as Dr. Wagner.

42. During this same time period, Forest took aggressive steps to publicize the positive results of the Wagner study. On August 27, 2001, Forest presented the Wagner study results to its Executive Advisory Board without making any mention of the contemporaneous negative Lundbeck results. Forest thereafter arranged for Dr. Wagner to present a poster summary of the Wagner study to various professional groups, including the American Psychiatric Association, the American College of Neurophyschopharmacology, and the Collegium Internationale Neuro-Psychopharmalogicum. In conjunction with these presentations, Forest coordinated the "placement" of news stories about the positive Wagner data in numerous national and local media outlets.

Forest's Continued Suppression and Misrepresentations Regarding Celexa and Lexapro Usage in Minors

43. Over the course of 2002, Forest arranged for Dr. Wagner to give promotional presentations on the pediatric use of Celexa and to serve as the chair of a seven-city Continuing Medical Education ("CME") program on treating pediatric depression. Forest also sponsored 20 CME teleconferences that addressed the Wagner study results.

44. Forest's simultaneous failure to disclosure the negative Lundbeck study results and wide publication of the positive Wagner study results caused Forest and its consultants to make false or misleading statements. For example, because no even Dr. Wagner was aware of the negative

Lundbeck data, she never discussed that data in her many Forest-sponsored talks addressing the pediatric use of Celexa and Lexapro. Her slide presentations addressed negative studies on pediatric use of other SSRIs, but falsely indicated that there were no negative studies on the pediatric use of Celexa.

45. Forest's failure to disclose the negative Lundbeck results to the members of Forest's Executive Advisory Board caused those members to make false or misleading statements in promotional teleconferences on Celexa and Lexapro. During the teleconferences, which were targeted to large numbers of physicians across the country, the Forest Executive Advisory Board members represented, based on the Wagner data, that Celexa was safe and effective for pediatric use even though, unbeknownst to them, the FDA had specifically rejected Forest's attempt to gain approval for such a claim because of the negative Lundbeck data.

46. During details to physicians, Forest's sales representatives made false or misleading representations by distributing off-label publications on the pediatric use of Celexa and Lexapro that did not include the negative Lundbeck data. Forest sales managers, also unaware of the Lundbeck data, directed the dissemination of these publications.

47. Forest had a Professional Affairs Department that responded to the health care providers inquires. Under the company's own written policy, the Professional Affairs Department was:

> *Required to provide balanced information* to help the health care practitioner (HCP) make the best decision on behalf of the patient. *For this reason, there is an ethical prohibition in "cherry picking" studies that are favorable to Forest products.* The Food and Drug Administration Division of Drug Marketing, Advertising, and Communications (DDMAC) monitors drug information departments to insure information provided to HCPs is balanced, and that it is not selective.

(Emphasis added.) Forest's failure to disclose the negative Lundbeck data to its Professional Affairs Department caused it to disseminate misleading information to physicians on the pediatric use of

Celexa and Lexapro. When physicians sought information from Forest's Professional Affairs Department in the years following the un-blinding of the Wagner and Lundbeck studies, the Professional Affairs Department responded with letters that cited only positive data. The letters cited just one double-blind placebo-controlled trial on the use of Celexa to treat pediatric depression, the Wagner Study. The letters never mentioned that there was another, negative, double-blind placebo controlled trial, the Lundbeck study.

48. Several senior Forest executives – including Lawrence Olanoff (then Forest's Chief Scientific Officer and now its President), Ivan Gergel (Vice President of Clinical Development and Medical Affairs), and Amy Rubin (Director of Regulatory Affairs) – reviewed the letters before the Professional Affairs Department disseminated them. All of these senior Forest executives knew about the negative Lundbeck data.

General Allegations Regarding Forest's Manipulation of the Scientific Literature; Ghostwriting, and; Direct to Consumer Promotional Materials Provided Both to Health Care Professionals and to Patients

49. Forest paid a medical writing firm to ghost-write an academic article on the Wagner study, and Forest arranged to have the article published in the June 2004 issue of *The American Journal of Psychiatry*, with Dr. Wagner listed as the lead author. The article did not mention that the only other double-blind, placebo-controlled trial on pediatric use of Celexa had shown no efficacy and had an incidence of suicide attempts and suicidal ideation among those taking Celexa that was almost three times higher than in the group taking the placebo.

50. On June 21, 2004, The New York Times, published a news story titled "Medicine's Data Gap – Journals in a Quandry; How to Report on Drug Trials." The story featured *The*

American Journal of Psychiatry article on the Wagner study, revealing the negative results of the Lundbeck study and noting that the Wagner article failed to mention them.

51. Three days after the story ran, Forest issued a press release acknowledging the existence of the Lundbeck study and its finding that Celexa "did not show efficacy versus placebo." That same day, Forest also disclosed the results of an earlier double-blind placebo-controlled study of Lexapro in children and adolescents. That study also failed to show efficacy in comparison to placebo.

52. By failing to disclose the Lundbeck study results, which raised serious questions about the efficacy and safety of Celexa, while simultaneously promoting the Wagner study, Forest told prescribing physicians a half-truth and hereby prevented them and the public from having all potentially available information when making decisions about how to treat a serious medical condition in pediatric patients.

53. Forest's conduct regarding the Lundbeck study results was consistent with the way it handled prior negative study on Celexa. Just a few months before the pediatric Lundbeck study was unblinded, senior executives from Forest and Lundbeck discussed whether publicly to disclose the negative results from a study of Celexa in a primary care population. The study included three groups: patients taking Lexapro, patients taking Celexa, and patients taking placebo. Although Lexapro showed efficacy versus the placebo in the study, Celexa did not. Minutes of a December 2000 meeting of senior Forest and Lundbeck executives show that Forest wanted to publicize only the Lexapro versus placebo results, while Lundbeck wanted the results from the entire study to be publicly disclosed. As Lundbeck executives noted a month earlier, "Forest made clear their concern

over distorting any data that could put Celexa in an unfavorable light." In May 2001, Lundbeck executives observed that "Forest are at the moment unwilling to release data where citalopram does not sufficiently surpass placebo." Forest ultimately prevailed over Lundbeck and, as it did later with Lundbeck's negative pediatric data, kept the negative Celexa versus placebo results confidential.

54. To obtain FDA approval for a drug, a drug must be demonstrated to be safe and effective for each of its proposed uses. The approved uses for a drug are limited to those uses identified in the FDA-approved product label. See 21 U.S.C. § 355(a),(b). "Off-label" use refers to the promotion of an approved drug for any purpose, or in any manner, other than what is described in the drug's FDA-approved labeling.

55. From 1998 through at least 2005, Forest engaged in a widespread campaign to promote Celexa and Lexapro for pediatric use, even though neither drug was approved for pediatric use and the science was, at best, inconclusive about the safety and efficacy of these drugs for pediatric use. Forest used its sales representatives to detail or target pediatric specialists; paid pediatric specialists to give promotional speeches to other physicians on pediatric use; selectively distributed publications on pediatric uses to pediatric specialists; misrepresented the safety and effectiveness of the drugs; and made extensive payments and gifts to induce physicians to prescribe Celexa and Lexapro for pediatric uses.

56. Forest knew that its off-label promotion for pediatric use was unlawful. Shortly before the FDA ordered the black box warning in September 2004, a Forest executive testified before Congress: "I want to emphasize that, because the FDA has not approved pediatric labeling for our products, Forest has always been scrupulous about not promoting the pediatric use of our

antidepressant drugs, Celexa and Lexapro. That is the law, and we follow it." In fact, Forest had been illegally promoting the pediatric use of Celexa and Lexapro throughout the preceding six years.

57. Forest assigned its sales representatives to specific geographic regions across the United States. Within each region, sales representatives encouraged specific doctors to increase their prescriptions of Celexa and Lexapro. A specific component of this marketing scheme included the promotion of Celexa and Lexapro for pediatric indications.

58. From 1998 through the end of 2004, the lists of physicians whom Forest directed its sales representatives to target, also known as "call panels" included thousands of child psychiatrists, pediatricians, and other physicians who specialize in treating children. Forest had more than 500,000 promotional sales calls or "details" with these pediatric specialists. The sales representatives documented these details through "call notes." Forest recorded thousands of call notes evidencing pediatric promotion. Examples of such notes include the following:

- "discussed cx [Celexa] use in children . . . and results of dr. karen wagner study regarding cx use for children and adolescents."
- "went over peds use, 0 drug interactions, less ae, less compliance issues for children, he is sold on that. Closed on keeping cx first choice."
- "went over Celexa children, the invitation to the winery."
- "[doctor] trying in children and asked if [Lexapro] could be dissolved in water for children. Told him to crush and put in apple sauce. Liked idea!"
- "discussed lx [Lexapro] brief and what he [is] using dosing w children . . . reinforced safety for children."
- "Let him know some child psychs are using LX for children."
- "Discussed children and adolescents with ADH[D] and how Lexapro fits in to treat the anxiety and depression and OCD."

- "dinner program [with child psychiatrist as speaker] at amato's with yale child study center."
- "Focus on Lexapro efficacy at just 10mg..great choice for child/adolescents."
- "Mainly sees children but always felt comfortable with CX & children – got his commitment to give [Lexapro] a fair clinical trial."
- "went over lxp use on children and efficacy."

Call notes such as these represent only some of the instances when sales representatives memorialized their illegal off-label promotion of Celexa and Lexapro. The call notes exemplify the tip of what was a much more pervasive and widespread off-label campaign.

59. Forest's headquarters office in New York maintained a list of "approved" promotional speakers that included numerous pediatric specialists. Forest sales representatives and managers identified speakers from these lists to organized promotional lunches and dinners on Celexa and Lexapro. As late as 2005, approximately 14% of Forest's 2,680 approved speakers were pediatric specialists. Many of the Forest promotional programs for Celexa and Lexapro explicitly focused on off-label pediatric uses: the programs had titles such as "Adolescent Depression," "Adolescent Treatment of Depression," "Updates in Depression," "Depression," "Treatment of Child/Adolescents," "New Age Depression Treatment," "Use of Antidepressants in Adolescents," "Benefits of SSRIs in Child Psychology," "Treating Depression and Related Illnesses in Children," "Adolescents, and Adults," "Celexa in CHP/Ped Practice," "Treating Difficult Younger Patients," "Treatment of Depression," "Assessment and Treatments of Suicidal Adolescents," and "Treating Pediatric Depression." Forest management approved each of these programs.

60. From 1999 through 2006, one pediatric specialists, Dr. Jeffrey Bostic, Medical Director of the Massachusetts Child Psychiatry Access Project at Massachusetts General Hospital, gave more than 350 Forest-sponsored talks and presentations, many of which addressed pediatric use of Celexa and Lexapro. Dr. Bostic's programs, which took place in at least 28 states, had topics such as "Uses of Celexa in Children" and "Celexa Use in Children and Adolescents." Forest also paid Dr. Bostic to meet other physicians in their offices in order to ease their concerns about prescribing Celexa or Lexapro off-label for pediatric use.

61. Dr. Bostic became Forest's star spokesman in the promotion of Celexa and Lexapro for pediatric use. As one sales representative wrote, "DR. BOSTIC is the man when it comes to child Psych!" Between 2000 and 2006, Forest paid Bostic over $750,000 in honoraria for his presentations on Celexa and Lexapro.

62. Forest augmented its off-label promotion efforts through extensive payments and gifts to physicians to induce them to prescribe Celexa and Lexapro. Forest's marketing department directed some of the kickbacks, such as honoraria for participation in advisory boards and in a large marketing study on Lexapro. Forest's sales representatives, often acting with the knowledge and encouragement of their managers, arranged for other kickbacks, such as restaurant gift certificates for physicians, lavish entertainment of physicians and their spouses, and grants to individual physicians.

Advisory Boards

63. Between 2000 and 2005, Forest hosted over 900 local or regional "advisory boards" on Celexa and Lexapro, with over 19,000 advisory board attendees that Forest called "consultants." Forest paid each "consultant" an honorarium of $500.

64. Ostensibly, Forest paid physicians to attend these advisory boards to get their feedback on the marketing of Celexa and Lexapro. In reality, as repeatedly reported in internal documents, Forest intended that the advisory boards induce the attendees to prescribe more Celexa and Lexapro.

65. In a May 2000 proposal for a series of 44 Celexa advisory boards, a Forest contractor, Intramed, wrote that the advisory boards, each with 20 physicians attendees, would "give Forest and opportunity to influence more physicians." Forest's marketing department approved this proposal. Later that year, Steve Closter, the Forest marketing executive who organized the advisory boards, wrote that the Celexa advisory boards begun in June 2000 had been successful and, as a result, "will become an even large part of the promotional mix in the future." For years thereafter, Forest's marketing department included the cost of advisory boards in its annual promotional budgets for Celexa and Lexapro.

66. With the early success of the advisory board programs, the Forest sales force enthusiastically used them to drive up sales. As one Forest District Manager told his Regional Director in a November 2000 planning document, he intended to conduct a local advisory board to "target the highest prescribers" in several of his territories because "there is no doubt that a program of this magnitude will increase Celexa market share." In approximately January 2002, a marketing strategy slide deck given to Forest's chief executive, Howard Solomon, quoted a Regional Director stating that, "[w]ell planned Advisory Board meetings will be key to our efforts of reaching hesitant physicians."

67. In June 2002, Forest's two Vice Presidents of Sales sent a memorandum to all sales managers observing that, notwithstanding new promotional guidelines for the industry, advisory boards remained among "the wealth of activities and programs that we can conduct that will impact physicians." Similarly, in August 2002, a Forest Regional Director sent an e-mail to his District Managers stating that, "with the new guidelines in place, Ad Boards have become even a more valuable resource, thus each one needs to be a home run! With you attention and focus, we can make [sic] maximize this opportunity!"

68. In the fall of 2002, to coincide with the launch of Lexapro, Forest conducted a series of 200 advisory boards reaching over 4,000 potential new Lexapro prescribers.

69. Forest monitored its return on investment, or "ROI," from the advisory boards. To conduct its ROI analyses, Forest measured the increase in prescriptions written by physicians that attended the local advisory boards, and then compared the value of those prescriptions to the cost – primarily the honoraria payments – of putting on the programs. A November 2000 ROI analysis of a single advisory board program reached the following conclusion:

> Post program the Ad Board group [24 attendees] wrote an average of 19.6% Celexa as measured by a 5-week 1st Rx average. This is an increase of 3.7% in share. At first glance, the share increase might not appear substantial. However, considering the volume of the SSRIs written by these physicians, 3.7% translates into almost 2000 new prescriptions on a yearly basis.

70. In May 2001, an internal ROI analysis of all of the Celexa advisory boards in 2000 found that "participants in the program prescribed nearly 14 additional prescriptions of Celexa vs. the control group over a seven-month period."

71. Three months later, in August 2001, the author of the ROI analysis reiterated to the Celexa marketing team that, "our goal is to increase the ROI on these advisory boards." That same month, a Forest Regional Director reported to the company's Vice President of Sales that three local advisory boards had "generated close to $30K" from just a subset of the attendees and that "the scripts will continue, and continue to generate additional $$$ and ROI."

72. After 2003, Forest stopped conducting ROI analyses of advisory boards because of concerns about memorializing illegal intent, but the company continued to use the same types of advisory board programs as a means of inducing doctors to prescribe Celexa and Lexapro. As a Forest Area Business Director noted in a September 2003 memorandum to his Regional Directors, "[w]e are not able to do as many Ad Boards as we have in the past, so it [is] critical that we get the best targets to the programs." Similarly, in March 2004, a Texas-based Forest District Manager reported to her Regional Director and fellow District Managers that she had met with her sales team about "the types of doctors" they wanted to recruit for an upcoming advisory board and that they had come "up with 40 doctors that are either high Celexa writers or can be converted/persuaded to write Lexapro." In August 2004, a Massachusetts District Manager wrote to his colleagues and sales team that, for an upcoming Lexapro advisory board, "we are looking for the best ROI."

The EXCEED Study

73. In 1998, Forest successfully used a so-called "seeding study" – a clinical study intended to induce participating physicians to prescribe the drug under study – as part of the promotional strategy for the launch of Celexa. With the launch of Lexapro in 2002, Forest sought to

replicate the success of the Celexa seeding study. Forest called the Lexapro seeding study EXCEED (EXamining Clinical Experience with Escitalopram in Depression).

74. In the planning stages for EXCEED, a senior Forest marketing executive wrote that the purpose of the study was to ensure a "fast uptake" for Lexapro. The overall Lexapro marketing plan, which was reviewed by the company's most senior executives, stated:

> Another component of the rapid uptake of Lexapro will be to encourage trial. The experience trial for Lexapro (EXCEED) will follow approval and will be larger in scope that the Celexa experience trial (EASE). More prescribers will have the ability to trial Lexapro on several patients to gain experience. Trial leads to adoption and continued usage of a product if a prescriber has successful results.

At the conclusion of EXCEED, Forest's marketing department planned to calculate the study's "ROI," i.e., the number of prescriptions generated as compared against the cost of funding the study.

75. To the extent the EXCEED trial had a scientific purpose, it was secondary to the purpose of inducing participating physicians to prescribe Lexapro. Forest conceived the study as a promotional tool and then sought out company scientists "to discuss possible endpoints/outcomes to look at for our early usage trial." Forest hired Covance, a contract research organization, to conduct the study, but, according to Covance's own study implementation plan, Covance, too, understood that "the primary goal of this trial is to provide experience to physicians." Similarly, Forest openly referred to the EXCEED trial as a "seedling" study in their internal communications.

76. Forest aimed the EXCEED study at 2,000 physicians. Under the study protocol, each participating physician could enroll up to five patients in the study, which would last eight weeks and involve three patient visits. After the first visit, the physician would fill out a one-page form with the patient's age, race, gender, and basic medical history, and Forest would pay the physician $50. After

each of the next two visits, the physician would fill out an additional page requiring the physician to write the date of the visit and to check one of seven boxes describing the change, if any, in the patient's condition. After the physician completed this additional page and the two other pages showing the patient's Lexapro dosing information and any adverse events or concomitant medications, Forest would pay the physician an additional $100. Forest ultimately allowed physicians to enroll up to ten patients in the study, so that physicians could make up to $1,500 for starting patients on Lexapro, plus an extra $100 if the physician dialed in to a pre-study teleconference.

77. By the time the EXCEED study was completed, Forest had made study participation payments to 1,053 physicians, who in turn put 5,703 patients on Lexapro during the course of the study.

Preceptorships

78. Between 1999 and 2003, Forest paid millions of dollars to physicians who participated in so-called "preceptorships." Each physician who participated in a preceptorship received a "grant" of as much as $1,000 per preceptorship.

79. Ostensibly, preceptorships were a training opportunity where Forest sales representatives would spend a half-day or full day with a physician and learn about how Celexa and Lexapro were used in practice. In reality, Forest sales representatives used the preceptorships to induce physicians to prescribe Celexa and Lexapro.

80. Forest was fully aware of how sales representatives actually used preceptorships. Company policy mandated that sales representatives fill out "Return on Investment (R.O.I.)" forms

to obtain approval to pay a doctor for a preceptorship. Each ROI form provided for a statement of the amount of the payment to the physician and a projection of how many incremental prescriptions the preceptorship would cause, along with an estimate of the dollar value of those prescriptions to Forest. Thus, the preceptorship ROI forms enabled Forest to evaluate whether a payment to a participating physician was intended to induce an increase in prescriptions sufficient to justify the cost to Forest. Senior Forest sales managers and headquarters staff reviewed and approved the completed preceptorship ROI forms.

81. The preceptorship ROI forms also provided for sales representatives to write narrative justifications for the preceptorship payments, included the following:

- "Dr. ___ is the managing partner of the '_____ Psychiatric Group' and is very influential among his colleagues in the _____ Hospital network. He currently averages @ 12 per week on 1st RX. His #s are trending up even till this day + we need to keep a good thing going as long as we are still getting this kind of growth from Dr. _____."

- "Dr. _____ is the largest prescriber of SSRI's in a 3 state area. . . . We are currently her first line SSRI. We must, however, continue to support her monetarily or this will not continue to e the case. . . . We have to keep the pressure on to continue to receive the growth we are getting with Dr. _____."

- "Dr. _____ is my largest prescribing Celexa physician. He is a high maintenance target and doing round tables and preceptorships will help me to keep his business and to continue to grow his business."

- "2 different preceptorships. Doc is 3rd ranked phys. in SSRI potential + bus had dropped. Needed his full attention."

- "Dr. _____ is my fourth largest SSRI writer. . . . A preceptorship will provide opportunity for rapport and for future detail time and sales."

- "#1 physician in Territory. . . . Dr. _____ is on the verge of writing a lot of Celexa. Will present new studies during preceptorship."

- "To influence doctor to Rx Celexa."

Forest approved all of these preceptorship payment justifications.

Lavish Entertainment and Gifts

82. During the period from 1998 through at least 2005, each Forest sales representative typically had a quarterly marketing budget of thousands of dollars to spend on physicians. As a Forest Regional Director put it in an April 2006 memo to his sales team, "we have a ton of promotional money." Forest sales managers put pressure on their sales representatives to spend their entire marketing budgets.

83. Prior to 2003, Forest sales representatives commonly spent their marketing money on fishing, golf, and spa outings for physicians, and on buying tickets to sporting events and the theater for physicians. Both prior to and after 2003, Forest sales representatives also attempted to induce physicians to prescribe Celexa and Lexapro by spending their marketing budgets on restaurant gift certificates, subsidies for physician office parties, and lavish entertainment that could be disguised on an expense report as meals accompanying a supposed exchange of scientific information. Examples of these various types of kickbacks include the following:

- In 1998, a District Manager (whom Forest later named to be its nationwide Director of Compliance) arranged for sales representatives in his district to give St. Louis Cardinals tickets to physicians on the condition, he said, that the tickets be "leveraged and sold as a reward for prescriptions" and that "A Solid Return on Investment can be demonstrated."

- In September 2002, a sales representative gave a high-prescribing child psychiatrist $1,000 gift certificate to Alain Ducasse, a New York restaurant that at the time was one of the most expensive in the United States.
- In June 2001, two Forest sales representatives took a physician and his three sons on a deep sea fishing trip off Cape Cod, Massachusetts.
- In June 2002, a sales representative arranged a salmon fishing charter cruise for four physicians in his territory.
- In February 2002, a sales representative purchased $400 in Broadway theater tickets for a physician and his wife.
- In February 2002, a Division Manager purchased $2,276 in Boston Red Sox tickets for his sales representatives to use, he said, "throughout the next six months with all of our key targets."
- From 2001 to 2005, Forest sales representatives in North Carolina repeatedly arranged social dinners for a psychiatrist who ran multiple offices and reportedly was the highest prescriber of Celexa and Lexapro in the state.
- From 2001 to 2005, Forest sales representatives in Louisiana repeatedly paid for a physician and his family to eat at one of the most expensive restaurants in the state; one of those sales representatives reported that the physician had promised he would "always rxlex [i.e., prescribe Lexapro] #1 as long [sic] as we have fun and take care of him."

84. All of this spending was intended to induce physicians to prescribe Celexa or Lexapro.

Forest's Prevention of Physicians' Exercise of Independent Professional Judgment on Behalf of Their Minor Patients

85. Virtually all physicians have access to the results of the Wagner Study. Forest's failure to disclose to these physicians the findings of the Lundbeck study, created the false impression that, based on the scientific evidence in Forest's control, there is no question about Celexa or Lexapro's safety and efficacy in treating children and adolescents, and therefore, the risk-benefit balance is well settled and generally favorable for this off-label use. This impression was reinforced by Forest's mis-characterization of much of the information it did disclose, its further concealment and suppression of negative information, and its Paxil-related targeting of psychiatrists who treat only pediatric patients.

86. Forest misled and deceived physicians and consequently the patients who relied on their professional judgment, including the Plaintiffs and the putative class herein. Forest deprived physicians, including Plaintiffs' physicians, of the information needed to evaluate the risks and benefits of prescribing Celexa and Lexapro for children and adolescents. By doing so, Forest deceived these physicians, irrespective of whether or not they would have prescribed Celexa or Lexapro if Forest had disclosed the material facts that were known at the time.

FIRST CAUSE OF ACTION
UNJUST ENRICHMENT

87. The allegations of each of the preceding and subsequent paragraphs are incorporated by reference as if fully set forth herein.

88. The misrepresentations and non-disclosures by Forest of the material facts detailed above have caused Forest to be unjustly enriched at the expense of Plaintiffs and the putative class members.

89. Forest's use of various forms of media to influence prescribing health care providers and advertise, promote and otherwise call attention to Celexa and Lexapro, deceptively misrepresented Celexa and Lexapro's attributes, performance/efficacy, characteristics and risks. Celexa and Lexapro could not and cannot perform as advertised and promoted, and Forest's promotion of Celexa and Lexapro constitutes unfair deceptive, untrue or misleading advertising. Forest's advertisements to the medical community deceived and continue to deceive that community and the consuming public. These advertisements and promotional efforts were disseminated for the purposes of unfairly gaining consumer market share by unfair competition. Forest either knew, recklessly disregarded, or reasonably should have known that such advertising was untrue and/or misleading.

90. As a result of the conduct described above, Forest has been and continues to be unjustly enriched at the expense of minor Celexa and Lexapro users, their guardians, and the general public, including the Plaintiffs and the putative class. Specifically, Forest has been unjustly enriched by the receipt of millions of dollars in monies and profits from selling Celexa and Lexapro for and to minors under misleading pretenses.

91. Forest has unjustly retained financial benefits at the expense of Plaintiffs, the putative class members, and the general public. Forest's unjust enrichment has caused damage to Plaintiffs and the class of persons and entities they intend to represent because Forest has retained the financial benefits from the sale of Celexa and Lexapro which Forest knew was no more effective than placebo and which Forest knew increased the risk of the serious adverse events described herein.

SECOND CAUSE OF ACTION
FRAUDULENT CONCEALMENT AND MISREPRESENTATION

92. The allegations of each of the preceding and subsequent paragraphs are incorporated by reference as if fully set forth herein.

93. Defendants fraudulently, negligently, falsely and/or deceptively represented or knowingly omitted, suppressed or concealed facts of such materiality regarding the risk-benefit profile and lack of efficacy of Celexa and Lexapro for pediatric use.

94. Defendants made assertions that were not in accord with the facts known to them at the time.

95. Defendants remained silent and/or offered misleading information despite its knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the risk-benefit profile and lack of efficacy of Celexa and Lexapro for pediatric use, and did so because the prospect of huge profits, all to significant detriment of Plaintiffs and members of the Class.

96. Defendants were otherwise careless, fraudulent, negligent, grossly negligent, and acted with willful and wanton disregard for the rights of Plaintiffs and members of the Class in the representations regarding the risk-benefit profile and lack of efficacy of Celexa and Lexapro for pediatric use.

97. Defendants failed to use reasonable care or competence in obtaining and communicating such information to Plaintiffs and members of the Class, and said information was, in fact, false and/or omitted material facts.

98. The material misrepresentations and omissions of defendants were likely to induce a reasonable person to manifest their assent without being fully informed of all the facts.

99. Plaintiffs and members of the Class justifiably relied upon the information provided by defendant to their economic detriment.

THIRD CAUSE OF ACTION
FRAUD

100. The allegations of each of the preceding and subsequent paragraphs are incorporated by reference as if fully set forth herein.

101. As previously alleged with particularity in this Complaint, each of the representations by Defendants was false, material to the pediatric marketability and commercial value of Celexa and Lexapro, and were intended by defendants to induce and mislead physicians to prescribe Celexa and Lexapro, Plaintiffs and Class Members to purchase Celexa and Lexapro for pediatric use, and Plaintiffs and Class Members to refrain from taking steps to seek alternative treatment options with a more favorable risk-benefit profile.

102. As alleged above, Defendants made representations known to be false, and with a reckless disregard for the truth, concerning the risk-benefit profile and lack of efficacy of Celexa and Lexapro for pediatric use.

103. Defendants knowingly omitted material facts concerning the safety and risk-benefit profile and lack of efficacy of Celexa and Lexapro for pediatric use from prescribing physicians, consumers, and the general public.

104. Defendants intended that others would rely on these material misrepresentations to the economic benefit of Defendants.

105. In reasonable reliance upon these material misrepresentations of Defendants, physicians were in fact induced to prescribe, and Plaintiffs and Class Members were induced to purchase Celexa and Lexapro for pediatric use.

106. As a direct and proximate consequence of Defendants' fraudulent misrepresentations, Plaintiffs and Class Members were damaged by: (1) failing to receive full value for their direct or indirect payment of money for Celexa and Lexapro for pediatric use: (2) incurring personal debt and/or out-of-pocket expenditures to purchase Celexa and Lexapro for pediatric use: (3) payment for Celexa and Lexapro for pediatric use on behalf of purchasers; and (4) foregoing safe and effective

alternative treatment options in reliance upon Defendant's misrepresentations that Celexa and Lexapro for pediatric use was effective and had a positive risk-benefit profile.

FOURTH CAUSE OF ACTION
VIOLATION OF CONSUMER PROTECTION ACT
New York's State Consumer Protection Act, N.Y. CLS Gen. Bus. §§ 349-350

107. The allegations of each of the preceding and subsequent paragraphs are incorporated by reference as if fully set forth herein.

108. Defendants violated New York's State Consumer Protection Act, N.Y. CLS Gen. Bus. §§ 349-350, in the alternative, under and by virtue of any applicable successor statute, by falsely misrepresenting deceptive material to the pediatric marketability and commercial value of Celexa and Lexapro, thereby inducing and misleading physicians to prescribe Celexa and Lexapro and Plaintiffs and Class Members to purchase Celexa and Lexapro for pediatric use, and Plaintiffs and Class Members to refrain from taking steps to seek alternative treatment options with a more favorable risk-benefit profile.

109. As a result of such violations, Plaintiffs and Class Members were caused to purchase Celexa and Lexapro for pediatric use, resulting in economic harm and forgoing safe and effective alternative treatment options in reliance upon Defendant's misrepresentations that Celexa and Lexapro for pediatric use was effective and had a positive risk-benefit profile.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs on behalf of the general public and themselves and all others similarly situated, pray for judgment and relief as follows:

1. An order certifying the class defined herein, appointing the Representative Plaintiffs as class representatives, and appointing Plaintiffs' undersigned counsel as counsel for the class;

2. Restitution, refund and/or reimbursement of all monies paid for purchase of Celexa and Lexapro for pediatric use and disgorgement of all monies acquired by means of Defendants' unlawful acts and through the sales of Celexa and Lexapro for use in minors to Plaintiffs and the punitive class members;

3. Other damages as allowed by law;

4. Reasonable attorneys' fees;

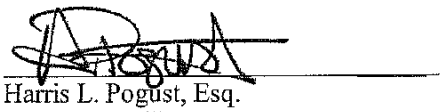
5. Costs of this suit;

6. Pre- and post-judgment interest; and

7. Such other and further relief as the Court deems necessary or appropriate.

Further, Plaintiffs hereby request a trial by jury on all claims set forth herein.

Dated: July 6, 2009



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